

Meeting Notes

Meeting with USDA/APHIS
January 09, 2003, 2-3PM, Room B, 6th Fl, CM#2

Purpose: Discuss and respond to USDA/APHIS's major concerns with EPA's comparative assessment.

USDA/APHIS's Major Concerns:

- Hazard versus risk assessment; if no exposure, no risk
 - *Have been careful to use "risk" or "potential risk only when exposure is a factor.*
 - *Made clear that this is a 'Preliminary Risk Assessment', and as such exposure is assumed rather than quantified. When more information on use patterns for different products and formulations is available, it will be considered.*
- Only information pertaining to negative effects in field studies and open literature was reported.
 - *We have ensured that the assessment presents an accurate and balanced presentation of the results from available reports. In fact, many of APHIS' own results and conclusions on the risks of zinc phosphide are included.*
- A toxicity classifications system based solely on a compound's inherent toxicity is misleading and the weaknesses of such systems should be explained in detail before they are used.
 - *We agree that the toxicity categorizations can be misleading, especially when characterizing risk. Thus, we have removed the WHO and PAN descriptors from the assessment.*
- When conducting a risk assessment, the EPA should state what levels of biological organization are targeted for protection (e.g., individuals or populations). The current assessment should define when protection of individuals or populations should be the target of a risk assessment.
 - *EPA has conducted and has reviewed ecological risk assessments at various levels of biological organization. One of the factors that determines the level of organization for any assessment is the amount and type of ecotoxicity and exposure data available for use in the assessment. For a preliminary assessment like this, the available data would limit the assessment to the individual. However, during the next phases of public review, we hope to be able to refine the assessment beyond the individual as additional data is submitted to the Agency.*
- EPA should ensure incidents in EIIS database are accurate and information is complete before using the data; double counting; tracking by product and a.i.
 - *EIIS, of course, contains reports of incidents for many pesticides and rodenticide incidents comprise only a portion of the total. We have re-reviewed the incident reports presented in the comparative assessment and believe that they are accurate, applicable, and there is no double counting. In addition, we have*

removed any misleading and inappropriate discussions of incidents. [Incidents are mainly used as evidence of exposure, not to quantify exposure. Characterization to this effect has been added. Also, have been careful to remove misleading implications of lethality. However, still note concern over potential sub-lethal effects.]

- EPA refuted the RRTF proposed threshold for brodifacoum but did not propose a new threshold; don't reference diphacinone data for brodifacoum analysis, thought the NWRC study is valid for the diphacinone analysis.
 - *We agree that the use of the diphacinone study for brodifacoum was inappropriate and it was removed from that section of the document. We believe that toxicity thresholds, based on both lethal and sublethal effects need to be established for each of the nine rodenticides.*
- Inaccurate reference to APHIS 6-gram bait pellet; should be USGS. Also, bait stations are not a practical option for rangeland/non-crop situations.
 - *We note USGS is experimenting with a 6-gram bait, and because this addresses mitigation, the statement has been deleted from the assessment. Mitigation will be addressed in a later phase of the reregistration process.*
- EPA should consider costs and benefits in addition to risks,
 - *Benefits will be addressed in a later phase of the reregistration process.*
- The draft document isn't consistent with what EPA has said elsewhere about the relative safety of Zinc Phosphide.
 - *EPA never stated that zinc phosphide is safe. Statement may have been made that it is relatively less risky based on secondary risk concerns to avian and mammalian predators when compared to some alternatives.*

N.B.

- Major changes in response to RRTF input include:
 - added characterization about exposure, and hazard versus risk
 - renamed the assessment (potential risks, comparative approach)
 - discussed uncertainties in data and results
 - added text to make clear what the assessment does and doesn't do
 - removed references to mitigation
 - emphasized that this is a preliminary assessment
 - highlighted information that could help refine the assessment

Other Concerns:

- Food processing plants
- In and around farm buildings

Next Steps

- EPA will work with OPMP to ensure that stakeholders interested in food processing plant

issues are kept informed

- Send courtesy copies of responses to comments to USDA /APHIS
- Open public comment period and send courtesy copies of revised assessment to key stakeholders